



# LIFE SCIENCES MADE TO CURE FOR BIOPHARMA

Accelerate market launch and maximize return on investment



## **DRIVE EFFICIENT PRODUCTION OPERATIONS WITH SHORTENED TIME-TO-MARKET, MINIMIZED PATIENT RISK, AND SUSTAINED PROFITABILITY.**

In today's pharmaceutical industry, organizations need to ensure and defend their market competitiveness as never before. They must maximize efficiency and reduce costs in their production processes, while at the same time, monitor and maintain high product quality and yield, minimize variability, and meet regulatory requirements worldwide. The **Made to Cure for BioPharma** Industry Solution Experience provides capabilities that enable organizations to shorten process development times, reduce tech transfer costs, and bring quality products to market with lower risk and improved profitability.

### **MAXIMIZE EFFICIENCY FOR IMPROVED OPERATIONS**

As companies look for ways to improve their competitiveness in the worldwide market, they focus on improving time-to-market and production process performance to maximize productivity and achieve high quality. Parameters that drive these outcomes must be continuously and reliably monitored, and business and technical reports and results must be easily exchanged with other groups in

the enterprise and with outsourced operations. In addition, Process Development, Manufacturing, and Quality teams depend on timely and reliable access to analyses and reports to support business and regulatory needs. Traditional manual methods jeopardize competitiveness because they cannot meet these needs without unacceptably high costs and risks.

## KEY BENEFITS:

- Create a robust and sustainable commercial production process using data-driven understanding of critical process parameters
- Monitor performance of critical production operations using process-specific analytics with automated alerts for improved decision making
- Identify and correct causes of variability in a validated environment using performance data from process development and production runs
- Collaborate across a global manufacturing and quality enterprise to improve efficiency by leveraging prior process knowledge

**Made to Cure for BioPharma\*** Industry Solution Experience minimizes non-value-added manual tasks, reduces the risk of errors and compliance enforcement costs, and promotes process understanding and knowledge sharing to reduce process and product variability. Ultimately, **Made to Cure for BioPharma** helps speed time-to-market and improve process economics and sustainability.

## Deliver desired business results

Design robust GMP processes with reduced tech transfer times, operating costs, and risks:

- Identify the Critical Process Parameters (CPPs) and operating ranges required for a sustainable production process and quality outcomes at commercial scale
- Scale-up and transfer processes with built-in quality through Quality by Design (QbD) for in-house and contractor operations
- Establish a data-driven culture for process knowledge sharing and collaboration
- Accelerate preparation and approval of science-based submissions to speed regulatory approval

\* **Made to Cure for BioPharma** is an industry solution experience available from the app(s) represented on the **3DEXPERIENCE®** platform: BIOVIA®

## Our 3DEXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

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## Enable pre-emptive action

Maximize process performance with visibility into process operations, quality, and compliance risks:

- Ensure robust processes through Continued Process Verification (CPV) with ongoing assurance of performance as designed
- Maximize productivity and minimize costs with automated alerts and monitoring-by-exception
- Establish a culture of ownership with visibility, communication, and collaboration across internal and external organizations
- Reduce the cost of periodic review and compliance reporting for Annual Product Review (APR) and Periodic Quality Review (PQR)

## Maximize sustainability

Drive process improvements with better understanding and control of process and product variability:

- Improve economics by identifying, reducing, and controlling sources of variability and maximizing yield, quality, and sustainability
- Accelerate preparation and approval of ongoing science-based submissions for Scale-Up and Post-Approval Changes (SUPAC)
- Reduce costs of deviations with near real-time data access and process-specific analytics
- Establish a culture of production and compliance excellence

To learn more about **Made to Cure for BioPharma** Industry Solution Experience provided by Dassault Systèmes, visit [www.3ds.com/made-to-cure-for-biopharma](http://www.3ds.com/made-to-cure-for-biopharma)